



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/000,004	05/02/2001	Photini-Effie Tsilibary	600.314USWO	4637

23552 7590 01/21/2003  
MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	000004 TSIL13ARTet al
Examiner	SAUNDERS 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Priority for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 9/30/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

56

Claim(s) 31-55 is/are pending in the application.

6/16/03  Of the above claim(s) 35-42, 49-51, 53-55 56 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 31-34, 43-48, 52 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3  Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

Applicant's election without traverse of Group II (claims 31-34, 43-48 and 52) in Paper No. 17 (filed 9/30/02) is acknowledged.

Claims 31-34, 43-48 and 52 will be examined for their embodiment employing an immunoassay –i.e. incubating a sample with an antibody. The examiner concurs with applicant's urgings that an election of species requirement for Group II is not proper.

Claims 31-34, 43-48 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims must be amended to encompass only the elected embodiment. Any dependent claims that would then fail to further limit (e.g. claim 43) would then require cancellation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Setty et al. (ASN Program & Abstracts 28<sup>th</sup> Annual meeting November 5-8, 1995, as cited on form 1449) in view of Matsuura et al. (4,894,326).

Setty et al. disclose the use of antibodies directed to alpha 2 intergrins in immunoprecipitation, and FACS methods (first paragraph). They teach that the patterns of expression of these markers are altered in tissue sections from diabetic rats (second paragraph), and they also teach that detecting these changes in integrin expression may help to predict the development of neuropathy in patients (third paragraph).

Matsuura et al. Teach the use of various antibodies against different forms of fibronectin in immunoprecipitation experiments to compare patterns of expression in different tissues (Figs. 4A-AD). They teach use of one or more of these antibodies in immunohistochemical methods (col. 5, lines 22-38). Also they teach the packaging of such antibodies in kits with containers (col. 5, lines 39-44 and claims 2 and 16).

Since it is conventional to provide antibodies for conducting immunoprecipitation and immunofluorescent methods in a kit, it would have been obvious to provide the anti-alpha—1 and alpha-2 antibodies of Setty et al. in kit. One would have been motivated to do so in order to conveniently provide antibody reagents necessary to detect the early development of neuropathy in diabetic patients, as suggested by Setty et al. At the least, even if potential use of the antibodies in diagnostic testing could not be confirmed, one would have motivated to supply such antibodies in Kit form, in order that various researchers in various clinical would be conveniently provided with the regents necessary to conduct the clinical testing studies suggested by Setty et al.

It is noted that, irrespective of whether one takes the Sept. 1995 publication date of the Setty et al. abstract or the Nov. 1995 meeting date of the presentation thereof as the date of public disclosure, both these dates post-date the July and Aug. 1995 filing dates of applicant's provisional applications 60/001387 and 60/001861. Neither of these provides any descriptive support, in any generic or specific sense, for claiming a kit. The Setty et al. abstract is thus properly cited as an intervening reference. Authorship and inventionship differ and thus render the Setty et al. abstract is a proper reference.

To overcome the reference of Setty et al., applicant may submit a declaration under rule 1.132, in accord with In re Katz 215 USPQ 14, to explain the role of authors Wu and Kim, who are authors of the reference but not inventor. Also applicant must clarify the invention role of Charon, who is an inventor but not an author.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rozzo et al. FEBS Letters, 332,263, 1993, as cited on form 1449 in view of Matsumura et al. (4,894,326).

Rozzo et al. Show the use of antibodies directed to the alpha 1 and alpha 2 integrins in an immunoprecipitation method (e.g. Fig. 4). Matsuura et al. Disclose the use of antibodies directed to various fibronectins in similar immunoprecipitation methods (e.g. Figs. 4A-4D) and they disclose that such antibodies can be packaged in a kit with containers (col. 5, lines 39-43 and claims 2 and 16). Since it is conventional to provide antibodies in kits it would have been obvious to provide the antibodies of Rozzo

et al. in a kit, in order to permit one to conveniently have these reagents provided for conducting similar experiments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Saunders/LR  
January 13, 2003

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644